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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DEFENDANTS C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S REPLY IN SUPPORT OF MOTION TO EXCLUDE THE TINLIN CASE-SPECIFIC OPINIONS OF ROBERT M. MCMEEKING, PH.D.

(ASSIGNED TO THE HONORABLE DAVID G. CAMPBELL)

(TINLIN BELLWETHER CASE)

(ORAL ARGUMENT REQUESTED)

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For the first time in any of the bellwether cases, in his deposition in this case, Dr. McMeeking candidly admitted he cannot say whether any of his purported IVC filter design alternatives would have prevented Ms. Tinlin's injuries. (*See, e.g.*, Exhibit A, McMeeking *Tinlin* Deposition (January 30, 2019) ("McMeeking Dep."[1]) at 60:13-17 ("Q. As we sit here today, Doctor, you cannot say to a reasonable degree of engineering certainty that the design changes you discuss in your report would have prevented Mrs. Tinlin's injuries, can you? A. That's correct.")) Likewise, Dr. McMeeking admitted he cannot say by what percentage Ms. Tinlin's risk of complications would have been reduced with the adoption of his purported alternative designs. (*Id.* at 60:18-21 ("Q. And you cannot say by what percentage the risk would have been reduced with these design changes, can you? A. That's correct."))

Because of these glaring admissions, Bard moved under *Daubert* and its progeny to exclude Dr. McMeeking's alternative design opinions -- including any opinions that a specific alternative design would have reduced the risk of complications experienced by Ms. Tinlin -- because those opinions do not "fit" this case. (*See* Bard's Mot. [Dkt. No. 15075] at 12-14.) Plaintiffs' Response completely ignores Bard's "fit" argument. (*See generally* Pls.' Resp. [Dkt. No. 15752].) Instead, Plaintiffs raise the strawman argument of disclosure, repeatedly identifying instances when Dr. McMeeking previously offered opinions about alternative IVC filter designs. (*See, e.g.*, Pls.' Resp. [Dkt. No. 15752] at 2, 4-7, 7-9.) But Bard never once argued that Dr. McMeeking's opinions are undisclosed.

Because Dr. McMeeking's alternative design opinions do not fit Ms. Tinlin's case, and because the methodology he used to reach his opinions is unreliable, Dr. McMeeking's alternative design opinions, including whether any specific alternative design would have reduced the risk of complications experienced by Ms. Tinlin, should be excluded under *Daubert* and Fed. R. Evid. 702. Dr. McMeeking should also be precluded

[1] When Bard filed its Motion [Dkt. No. 15075] on February 1, 2019, Bard had not yet received the final transcript of Dr. McMeeking's January 30, 2019 deposition. Bard's Motion, therefore, cites to the rough transcript of Dr. McMeeking's deposition. Bard has since received the final transcript and will cite to it throughout this Reply Brief.

from opining about Bard's state of mind, including specifically opinions about Bard's alleged "choices" in designing the Recovery without the design attributes that Dr. McMeeking alleges are better alternatives.

A. Plaintiffs Ignore, and Therefore Concede, Bard's "Fit" Argument.

Bard's first argument in its Motion is that Dr. McMeeking's alternative design opinions are pure speculation as applied to Ms. Tinlin's case because he cannot opine whether any of his alternative designs or alternative filters are viable or would have reduced or prevented Ms. Tinlin's injuries. (*See* Bard's Mot. [Dkt. No. 15075] at 12-14.) If Dr. McMeeking were permitted to offer his alternative design opinions in the *Tinlin* matter, the jury would be forced to guess whether any of his purported alternative designs or alternative filters would have benefitted Ms. Tinlin at all. Because of this significant gap in Dr. McMeeking's opinions, they fail to meet *Daubert*'s "fit" requirement. *See Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1321 n.17 (9th Cir. 1995) ("Federal judges must [] exclude proffered scientific evidence under Rules 702 and 403 unless they are convinced that it speaks clearly and directly to an issue in dispute in the case, and that it will not mislead the jury."); *see also id.* at 1320-22 (excluding plaintiffs' experts for lack of "fit" because the experts could not say whether ingestion of the defendant's drug caused plaintiffs' alleged injuries).

Plaintiffs utterly fail to address or respond to this argument. This failure alone serves as an independent basis to grant Bard's Motion and exclude Dr. McMeeking's alternative design opinions. *See, e.g.*, *Francois v. United States*, No. CV-16-02936-PHX-BSB, 2017 WL 467976, at *6 (D. Ariz. Feb. 3, 2017) ("Plaintiff did not respond to these arguments in her response to the motion to dismiss. Under LRCiv 7.2(i), the Court may treat Plaintiff's failure to respond as a waiver of that issue and consent to Defendants' argument" (citing *Doe v. Dickenson*, No. CV-07-1998-PHX-GMS, 2008 WL 4933964 at *5 (D. Ariz. Nov. 14, 2008))); *Currie v. Maricopa County Cmty. College Dist.*, No. CV-07-2093-PHX-FJM, 2008 WL 2512841, at *2 n.1 (D. Ariz. June 20, 2008) ("Plaintiff does not respond to this argument, and her failure to do so serves as an independent basis upon

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which to grant [the] motion."); *E.E.O.C. v. Eagle Produce, L.L.C.*, No. CV–06–1921, 2008 WL 2796407, at *2 (D. Ariz. July 18, 2008) ("Parties must come forward with their points and authorities in support of or in opposition to a motion."); *see also Myers v. United States*, 673 F. App'x 749, 752 (9th Cir. 2016) ("[F]ailure to address an issue in an answering brief may waive any argument on the issue.").

Because Dr. McMeeking fails to apply his alternative design opinions to the facts of Ms. Tinlin's case, his opinions do not meet the "fit" requirement under *Daubert*. Accordingly, this court should grant Bard's Motion.

B. Dr. McMeeking's Alternative Design Theories Are Unreliable, Not Undisclosed.

Plaintiffs do not contest that Dr. McMeeking performed no testing at all of his purported alternative designs. Plaintiffs do not contest that Dr. McMeeking prepared no specific designs, drawings, specifications, or prototypes of his alternative designs. And Plaintiffs do not contest that Dr. McMeeking has no proposed details or dimensions or specifics whatsoever.[2]

Dr. McMeeking's deficiencies with his purported alternative designs are all the more glaring given that he candidly admits he cannot say whether any of his designs or alternative filters would have reduced or prevented Ms. Tinlin's injuries, or are otherwise viable alternatives for her. Ultimately, Dr. McMeeking's alleged alternative designs are not truly "designs" for Ms. Tinlin at all: They are mere ideas.

[2] Plaintiffs argue that Dr. McMeeking has conducted "calculations" of the "chamfer" that he suggests as an alternative design. (Pls.' Resp. [Dkt. No. 15752] at 5.) But all Dr. McMeeking has done is consider "the difference between a radius of curvature of 5 microns and one in which . . . the radius of curvature is very large." (Exhibit B, Dr. McMeeking MDL Deposition (July 6, 2017) at 39:9 to 40:3.) When asked to specify what he meant by a "very large" radius of curvature, Dr. McMeeking clarified that he "modeled [] a case where the chamfer is having ***no effect*** on raising the strains . . . in the arms where the arms are in contact with the chamfer," (*id.* at 40:16-22), i.e., an "infinit[e]" curvature, something that Dr. McMeeking admits is "not practical for a filter." (*Id.* at 40:4-15.) And Dr. McMeeking admits that his chamfer, without any other design changes, "would not necessarily prevent a fracture." (Ex. A, McMeeking *Tinlin* Dep., at 48:4-7.) It is also undisputed that Dr. McMeeking has never tested the performance of a proper chamfer on a filter. Finally. Dr. McMeeking admits he has performed no calculations regarding caudal anchors, penetration limiters, or a two-tiered design. (*Id.* at 47:3-14.)

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i. Bard Did Not Argue "Nondisclosure."

Instead of addressing these concessions by Dr. McMeeking, Plaintiffs' Response raises the specter of "nondisclosure," and then rebuts it by arguing that "Dr. McMeeking has previously disclosed the very opinions as to alternative design features that are set forth in his *Tinlin*-specific report." (Pls.' Resp. [Dkt. No. 15752] at 4; *see also, e.g.*, *id.* at 5 ("Dr. McMeeking has testified to these very design features in the bellwether trials.") But Bard's Motion is based on *Daubert* and the unreliability and lack of fit of Dr. McMeeking's opinions.[3] Bard did not argue that Dr. McMeeking's opinions are undisclosed. Plaintiffs have cited no legal authority for the proposition that an expert's opinions are excused from *Daubert*'s reliability and fit requirements merely because the expert has offered the opinions previously.

ii. Dr. McMeeking's Failure to Test, Design, Prototype, or Create Drawings or Specifications of His Alternative Designs Renders His Opinions Unreliable.

Plaintiffs baldly assert that Dr. McMeeking does not need to test his designs for them to be reliable. (Pls.' Resp. [Dkt. No. 15752] at 6.) In support of this claim, Plaintiffs argue, without citing any authority, that "[Dr. McMeeking's] assessment was performed in the manner that is typically applied by mechanical engineers during the design and verification stages of the manufacturing of devices such as biomedical implants," (*id.* at 3-4), and that he "applied principles of sound mechanical engineering in arriving at his conclusions." (*Id.* at 7.)

Dr. McMeeking's own testimony belies Plaintiffs' argument that proper testing is not a necessary part of the "design and verification stages" of medical device development. Indeed, Dr. McMeeking has testified that alternative designs such as caudal anchors or penetration limiters need to be designed to be effective, and that one must test the designs to ensure safety and effectiveness:

[3] Bard is raising this *Daubert* motion in this case because Dr. McMeeking, for the first time, stated in testimony that he could not determine whether any of his purported alternative designs or alternative filters are viable for Ms. Tinlin, or would have reduced or prevented her injuries.

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Q. And as an engineer in understanding the product development process, as you do, you would agree it's not just a matter of Bard snapping its fingers and suddenly limiters and anchors appear and work fine; correct?
A. That's correct.
Q. It ***requires some development work in the design and testing*** of those features; correct?
A. ***That's correct***.
Q. And ***design and testing to ensure that the addition of those features do not compromise the safety or effectiveness*** of the device in other ways; correct?
A. ***That's correct***.

(McMeeking Dep. at 73:21 to 74:7 (emphasis added).)

Q So, therefore, you do not believe it's sufficient for a filter to simply have some sort of anchors or penetration limiters in order to improve safety; correct?
A That's correct. ***They need to be designed to be effective***.
Q They have to be the proper size; correct?
A Correct.
Q They have to be a size that does not compromise the performance or the safety in some other way of the device; correct?
A Well, they -- they should be designed in such a way that they reduce the risks to the extent practicable and that -- that that is balanced against the benefits of the filter.
Q And you have made no effort in this litigation to figure out the precise dimensions or size of these design features that would accomplish what you just described?
A That's correct.

(McMeeking Dep. at 80:11 to 81:3 (emphasis added).)

Dr. McMeeking's above testimony is consistent with FDA's "Design Control Guidance for Medical Device Manufacturers," (March 11, 1997).[4] In that Guidance, FDA states that the "basis of [design] verification is a three-pronged approach involving ***tests***, inspections, and analyses." (*Id.* at 30 (emphasis added).) Testing a design is important

[4] Available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070642.pdf (last accessed March 13, 2019).

because "verification testing establishes conformance of design output with design input." (*Id.* at 31.) Moreover, testing is a mandatory step of the design control process as stated in the Federal Quality System Regulations. 21 C.F.R. § 820.30(g) states as follows: "Design validation shall ensure that devices conform to defined user needs and intended uses and ***shall include testing of production units*** under actual or simulated use conditions." (Emphasis added.)[5]

Finally, citing Dr. McMeeking's testimony elicited on redirect examination by Plaintiffs' counsel, Plaintiffs argue that testing (an unspecified, undrawn, and undesigned) "device[] or design feature" is somehow not necessary. However, that testimony in fact contradicts Plaintiffs' argument:

> Q. And do mechanical engineers in your role typically carry out bench testing or animal testing?
> A. Well, ***many of them carry out bench testing***. But animal testing would be an unusual pursuit for a mechanical engineer of my background and professional activities.

(McMeeking Dep. at 110:11-16 (cited in Pls.' Resp. [Dkt. No. 15752] at 6) (emphasis added).[6])

At bottom, Dr. McMeeking's alternative design "ideas" are nothing more than a potential design input without any determination as to feasibility, effectiveness, or safety.[7]

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[5] FDA has also highlighted the importance of pre-clinical testing of IVC filters specifically. In its 1999 "Guidance for Cardiovascular Intravascular Filter 510(k) Submissions," FDA states that it is the manufacturer's "responsibility to conduct [pre-clinical] testing which adequately addresses the concerns outlined [in the Guidance] as well as any others which may arise due to the unique design of the given device." Available at https://www.fda.gov/RegulatoryInformation/Guidances/ucm073776.htm (last accessed March 13, 2019).

[6] Even Dr. McMeeking's qualification that animal testing would be an "unusual pursuit ***for a mechanical engineer of my background and professional activities***" is telling. As Bard's engineering witnesses have testified at the three bellwether trials, animal testing is a common step in the development of an implantable medical device. That an academic like Dr. McMeeking would not normally perform animal testing himself comes as no surprise.

[7] Plaintiffs argue that, "as Bard well knows," Dr. McMeeking's proposed design features have been incorporated in later generation devices. (Pls.' Resp. [Dkt. No. 15752] at 5-6.) But as Plaintiffs are well aware, Dr. McMeeking has opined that these design features on Meridian are not effective (McMeeking Dep. at 77:23 to 78:1), and that Denali suffers from the same problems as Bard's earlier generation filters at least in part because its

Moreover, Dr. McMeeking cannot say whether any of his alternative designs or alternative filters would have made a difference ***in Ms. Tinlin's case***. His alternative design ideas are not reliable under *Daubert* and should be excluded.

iii. This Court Has Not Admitted Dr. McMeeking's Alternative Design Opinions Over a *Daubert* Objection.

Plaintiffs repeatedly claim that this Court has deemed "admissible" Dr. McMeeking's alternative design opinions and found them "appropriate" for the jury. (Pls.' Resp. [Dkt. No. 15752] at 2 ("[T]his Court has previously determined that Dr. McMeeking's opinions on these topics are appropriate."); *id.* at 5 ("The opinions on these design features have already been determined admissible by this Court." (citing the *Hyde*, *Jones*, and *Booker* trial transcripts)).)

Plaintiffs' argument is misleading. While this Court has ruled on the admissibility of Dr. McMeeking's alternative design opinions at the *Jones* and *Hyde* trials, the rulings were overruling ***nondisclosure*** objections, not ***Daubert*** or ***Rule 702*** objections.

Specifically, in *Jones*, when Plaintiffs' counsel began to elicit testimony regarding "alternative design elements," Bard's counsel objected that it was "outside the scope of the report." (Exhibit C, *Jones* Trial Tr. at 403:17 to 404:3.[8]) After a sidebar, the Court admitted the testimony. (*See id.* at 407:2-4.) Similarly, in *Hyde*, Bard's counsel's objection to Dr. McMeeking's alternative design opinions was non-disclosure. (*See* Pls.' Resp., Ex. F [Dkt. No. 15752-6], at 619:1-4.[9]) With respect to *Booker*, nowhere in the

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penetration limiters and caudal anchors are inadequate. (*Id.* at 78:19-21, 80:6-10.) Plaintiffs also point to the Gunther Tulip device that has caudal anchors or penetration limiters, (Pls.' Resp. [Dkt. No. 15752] at 6), but Dr. McMeeking considers that filter defective, too. (McMeeking Dep. at 72:2-5.)

[8] Although Plaintiffs' Response attached the Court's ruling on admissibility, it fails to include the portion of the transcript that reflects Bard's objection. (*See* Pls.' Resp., Ex. G [Dkt. No. 15752-7].)

[9] Plaintiffs argue that Bard's counsel has conceded as "fair game" Dr. McMeeking's opinions and testimony concerning "poor design," "inadequate testing," and "improper internal assessment" of Bard's IVC filters. (Pls.' Resp. [Dkt. No. 15752] at 8 (quoting *Hyde* Trial Tr. at 524:7-25.) But those areas of opinion are distinct from the opinion that a specific alternative design or filter would have reduced or prevented a plaintiff's risk of complications. Moreover, the context of the sidebar discussion quoted by Plaintiffs' Response is, again, whether Dr. McMeeking's opinions were adequately disclosed in his

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approximately 30 pages of trial transcript that Plaintiffs cite, (Pls.' Resp. [Dkt. No. 15752] at 5 (citing *Booker* at 569:25 to 598:19)), does Bard object to the testimony, nor does the Court rule on admissibility or "appropriateness" of the testimony.

Finally, regardless of Dr. McMeeking's prior trial testimony, the *Tinlin* bellwether trial is a new case, with new opinions and new deposition testimony from Dr. McMeeking. His deposition testimony in this case makes clear that his alternative design opinions do not fit Ms. Tinlin's case, and they are unvalidated, unverified, and unreliable. His opinions should be excluded.

C. Bard's Motion Specifies the Opinions Bard Seeks to Exclude.

Both in the introduction and the conclusion, Bard's Motion sets forth Dr. McMeeking's specific opinions that Bard seeks to exclude. Those opinions, again, are as follows: (1) Alternative designs, including whether any specific alternative design would have reduced the risk of complications experienced by Ms. Tinlin; and (2) Bard's alleged "choices" in designing the Recovery without the design attributes that Dr. McMeeking alleges are better alternatives.

Plaintiffs' Response claims that Bard has "failed to identify with specificity the opinions that it complains are inadmissible" (Pls.' Resp. [Dkt. No. 15752] at 2), yet, Plaintiffs' Response starts by ***quoting*** Bard's conclusion that articulates the precise opinions Bard seeks to exclude. (*Id.* at 1.)

To be clear, the "alternative designs" that Bard seeks to preclude Dr. McMeeking from discussing at trial are the "caudal anchors, penetration limiters, two-tier design, and a better (smoother and rounded) chamfer at the mouth of the 'cap' on the filter" that Dr. McMeeking identifies in his *Tinlin* Report at page 3 (*see* Bard's Mot., Ex. A (McMeeking's *Tinlin* Report) [Dkt. No. 15075-1], at 3; *see also* Bard's Mot. [Dkt. No. 15075] at 2 (reciting these same designs and citing Dr. McMeeking's Report)), as well as

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Report. (*See* Exhibit D, *Hyde* Trial Tr. at 525:1-19 (". . . So this is a new opinion. . . that is a nondisclosed opinion in the case.").) Plaintiffs' Response and Exhibit F does not include the full sidebar that makes clear the basis for Bard's counsel's objection.

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the designs of the "Simon Nitinol Filter, the Cook Gunther Tulip filter, the Greenfield filter, and the Cook Bird's Nest filter" that Dr. McMeeking identifies at page 3 of his *Tinlin* Report. (*See* Bard's Mot., Ex. A (McMeeking's *Tinlin* Report) [Dkt. No. 15075-1], at 3.) Bard also seeks to preclude Dr. McMeeking from opining that any of these alternative designs or filters "would have helped to mitigate or eliminate the failures [he] identified and that occurred in Mrs. Tinlin's filter." (*Id.*) Finally, Bard's Motion seeks to preclude Dr. McMeeking from offering improper opinions about Bard's "choices" it allegedly made in designing the Recovery Filter. These opinions are at page 2 of Dr. McMeeking's *Tinlin* Report. (*See* Bard's Mot., Ex. A (McMeeking's *Tinlin* Report) [Dkt. No. 15075-1], at 2 ("Bard made a choice to design the Recovery filter without caudal anchors," "Bard made a choice to design the Recovery filter without perforation limiters," and "Bard made a choice to design the Recovery filter without features that would prevent and/or minimize tilt.").)

D. Dr. McMeeking's Opinions About Bard's "Choices" Are Improper Opinions About Bard's State of Mind.

Dr. McMeeking admitted that he has no evidence that Bard considered and rejected alternative design features such as caudal anchors, penetration limiters, or other features to minimize or prevent tilt. (*See* McMeeking Dep. at 82:23 to 83:2, 83:24 to 84:2; 84:20-23.) He agrees he cannot testify as to Bard's motives, intent, or state of mind with respect to Bard's design of Recovery. (*See, e.g., id.* at 83:3-13.)

Plaintiffs claim that Dr. McMeeking's opinions about Bard's choices are not "corporate motive or intent testimony." (Pls.' Resp. [Dkt. No. 15752] at 10.) But this argument ignores the plain meaning of the word. A "choice" is simply the noun version of the verb "to choose."[10] The first definition of to "choose" is "to select freely and after consideration."[11] Thus, based on the plain, dictionary meaning of the term "choice," Dr.

[10] *See* Merriam-Webster's Online Dictionary, available at https://www.merriam-webster.com/dictionary/choice (last accessed March 13, 2019).

[11] *See* Merriam-Webster's Online Dictionary, available at https://www.merriam-webster.com/dictionary/choose (last accessed March 13, 2019).

McMeeking seeks to offer ***expert opinion*** regarding Bard's selection of design features for the Recovery after consideration. Such opinions would necessarily overstep into Bard's state of mind, intent, and motives. They should be excluded.

CONCLUSION

For the reasons stated above and in Bard's Motion [Dkt. No. 15075], Bard respectfully asks this Court to Grant the Motion and issue an order precluding Dr. McMeeking from offering opinions regarding the following: (1) Alternative designs, including whether any specific alternative design would have reduced the risk of complications experienced by Ms. Tinlin; and (2) Bard's alleged "choices" in designing the Recovery without the design attributes that Dr. McMeeking alleges are better alternatives.

RESPECTFULLY SUBMITTED this 15th day of March, 2019.

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CERTIFICATE OF SERVICE

I hereby certify that March 15, 2019, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/ Richard B. North, Jr.
Richard B. North, Jr.